Remarks

A. Period For Reply

A shortened statutory period for reply was set to expire three months from the mailing date of the Office Action of November 18, 2005. Three months from November 18, 2005 was February 18, 2006. March 18, 2006 fell on a Saturday. This Amendment and Remarks is being facsimile transmitted to the USPTO on Monday, March 20, 2006 along with a petition for an extension of time for one month.

B. Status

The Office Action of November 18, 2005 was nonfinal.

C. Disposition of Claims

Claims 21, 23, 26, 28, 30, 33, and 35-46 are pending.

D. Application Papers

Approval of the formal drawings at the appropriate time would be appreciated. Formal drawings were filed with the filing of this case on December 12, 2003.

E. Priority under 35 U.S.C. §§ 119 and 120

This case claims the benefit under 35 U.S.C. 120 of U.S. Patent Application No. 09/452,656 filed December 1, 1999. An Application Data Sheet having such claim was filed with the filing of this case on December 12, 2003. Further, the Preliminary Amendment filed with the filing of this case on December 12, 2003 asked that the specification be amended to include such claim.

As to foreign priority, this case does not claim foreign priority.

F. Attachments

Three PTO-1449 forms were filed with the filing of this case on December 12, 2003. All three of these forms were signed by the Patent Office and returned with the Office Action of September 15, 2004, and all of the references listed on such forms have been initialed. This is very much appreciated.

G. The Office Action

G.1. Response to Arguments

On page 2 of the Office Action of November 18, 2005, MPEP 2113 is noted, which states that the patentability of a product does not depend upon its method of production. In light of this standard, applicant has removed the process limitation relating to the steps of submerging in independent claims 21, 26, 28, 33 and 36.

On page 3 of the Office Action of November 18, 2005, the Examiner has noted applicant's side-to-side comparison of patented claims with application claims. The Examiner pointed out that a major limitation, found in claim 1 of U.S. Patent No. 6,692,527, has not been incorporated into current claim 21. Such major limitation is:

Each of independent claims 21, 26, 28 and 36 has been amended to recite the following limitation:

- wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

Accordingly, such major limitation has been placed in independent claims 21, 26, 28 and 36. The Examiner has noted that said

limitation distinguished over the McGhan et al. reference.

G.2. Claim Rejections - 35 USC § 112

On pages 3-5 of the Office Action of November 18, 2005, claims 21, 23, 26, 28-33 and 35-46 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In response, the subject matter here at issue has been deleted from independent claims 21, 26, 28, 33 and 36. Hence it is respectfully submitted that the claims are now in compliance with 35 U.S.C. 112, first paragraph.

G.3. Claim Rejections - 35 USC § 102

G.3.a. The McGhan et al. reference

On pages 5-6 of the Office Action of November 18, 2005, claims 21, 23, 26, 28-33, and 35-46 (all claims) were rejected under 35 U.S.C. 102(b) as being anticipated by McGhan et al. (3,852,832). As to such, applicant has now added the following limitation that, according to the Examiner, distinguishes over McGhan et al.:

- wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

The above noted limitations have been added to independent claims 21, 26, 28, 33, and 36. It is thus respectfully submitted that such claims, along with their dependent claims, are allowable over the McGhan et al. reference.

G.3.b. The Prescott reference

On pages 6-7 of the Office Action of November 18, 2006, claims 21, 23, 26, 28-33, and 35-46 (all claims) were rejected under 35 U.S.C. 102(b) as being anticipated by Prescott (5,522,896).

In such a rejection, it was stated that Prescott teaches a breast implant comprising a fillable "envelope." It was further stated that "The implant is fully capable of being sealable after being filled." However, as specifically discussed in the Amendment and Remarks of January 16, 2005, the Prescott reference does not teach an implant that can be filled with fluid.

G.3.b.i. The Prescott breast prosthesis of Figure 1a

The Prescott breast prosthesis of Figure 1a comprises a biocompatible composite material dispersed through a matrix of elastomeric material. There is no teaching here of one side that is one-piece with another side being smooth relative to the other side or thick relative to the other side.

G.3.b.ii. The Prescott breast prosthesis of Figure 1b

Where coating 4 is only on proximal side 6 of the breast prosthesis 2 shown in Figure 1b, then such proximal side coating 4 is not one-piece with the other side of the Prescott prosthesis 2.

G.3.b.iii. The Prescott breast prosthesis of Figure 1c

Where coating 4 is on both of the sides, as shown in Figure 1c of Prescott, then two things are true: 1) there is no teaching that one side is smooth relative to the other side; and 2) there is no teaching that one side is thick relative to the other side.

G.3.b.iv. The Prescott reference teaches a prosthesis

The Prescott reference teaches a prosthesis. A prosthesis is an artificial device used to replace a missing body part, such as a limb, tooth, eye, or heart valve.

G.3.b.v. The Prescott prosthesis has a predetermined shape

The Prescott prosthesis comprises a biocompatible composite material having a predetermined shape. Please see column 4, lines 42-44 of the Prescott reference. The composite material can be provided to the physician previously molded, whereby the physician could trim or deform the molded composite material before or during positioning. Please see column 7, lines 21-24 of the Prescott reference. The composite material can be provided to the physician uncured, molded by the physician and subsequently cured either at room temperature or by addition of a catalyst. Please see column 7, lines 24-27 of the Prescott reference. Please note that different shapes of the Prescott figures: a breast prosthesis, a chin implant, a cheek augmentation device, an ossicular replacement prosthesis, middle ear prosthesis, nasal prosthesis, and finger joint prosthesis.

G.3.b.vi. The Prescott prosthesis, that may be open-cell, is not filled with fluid

The Prescott reference does not teach an implant that can be filled with fluid. The Prescott reference teaches an elastomeric material that may be in the form of an open-cell foam. Please see column 4, lines 57-58 of the Prescott reference. It is respectfully submitted that an open-cell cannot contain fluid. Even though Prescott teaches other materials, such as closed-cell foam, there is no teaching to contain fluid in such other materials.

Moreover, the Prescott reference does not teach an implant that can be filled with fluid to provide a three-dimensional

shape. It is respectfully submitted that "a conventional silicone breast prosthesis" as described in column 5, line 60 of the Prescott reference does not teach a fluid filled implant.

G.3.b.vii. Summary

For the above noted reasons, it is respectfully submitted that independent claims 21, 26, 28, 33, and 36, along with their dependent claims, are allowable over the Prescott reference.

G.3.c. The Baker reference

On page 7 of the Office Action of November 18, 2006, claims 28, 30, 32, 39 and 44 were rejected under 35 U.S.C. 102(b) as being anticipated by Baker (5,026,394).

Independent claim 28 has been amended by fully incorporating dependent claim 29 therein such that claim 28 now includes the following limitation:

- g) wherein the posterior side comprises a textured exterior surface portion.

It should be noted that claim 31 has been canceled so to minimize inconsistency issues with independent claim 28.

It is thus respectfully submitted that the Baker reference does not disclose such a feature and that independent claim and its dependent claims are now allowable over the Baker reference.

G.4. Claim Rejections - 35 USC § 103

On pages 7-8 of the Office Action of November 18, 2005, claims 42-46 were rejected under 35 U.S.C. 103(a) as being unpatentable over McGhan et al. (3,852,832) or Prescott (5,522,896). This rejection is respectfully traversed. Additionally, these claims are dependent claims and the arguments as to their respective independent claims are incorporated

herein.

G.5. Conclusion

In conclusion, a side-to-side comparison is set out below. This side-to-side comparison shows the similarity of the independent claims of U.S. Patent No. 6,692,527 to the present application independent claims. A Terminal Disclaimer To Obviate A Double Patenting Rejection Over A Prior Patent was filed in this case on January 16, 2005.

Independent claims
of U.S. Patent No. 6,692,527

1. A breast implant for being implanted within a body, wherein the body includes front, rear, right and left sides, wherein the breast implant comprises:

a) an envelope having at least two sides, wherein the envelope is fillable with fluid to provide a three-dimensional shape to the envelope;

b) wherein one of the sides of the envelope comprises a relatively smooth surface;

c) wherein the other of the sides of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the envelope has been implanted such that the envelope is restrained from rotating and such that the relatively smooth surface may be oriented as desired within the body;

d) wherein one of the sides of the envelope is thicker than the other of the sides of the envelope, wherein the thicker side of the envelope comprises the relatively rough surface, and wherein the thinner side of the envelope comprises said relatively smooth surface; and

e) wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

Independent claims
of the present case, which claims
benefit of U.S. Patent No. 6,692,527

21. (currently amended) An implant for being implanted within a body, wherein the body includes front, rear, right and left sides, wherein the implant comprises:

a) an envelope having at least two sides, wherein the envelope is fillable with fluid to provide a three-dimensional shape to the envelope;

b) wherein one of the sides of the envelope comprises a relatively smooth surface;

c) wherein the other of the sides of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the envelope has been implanted such that the envelope is restrained from rotating and such that the relatively smooth surface may be oriented as desired within the body;

d) wherein one of the sides of the envelope is thicker than the other of the sides of the envelope, wherein the thicker side of the envelope comprises the relatively rough surface, and wherein the thinner side of the envelope comprises said relatively smooth surface;

e) wherein the envelope is sealable after being filled with said fluid, and wherein said thicker side is one-piece with said thinner side; and

f) ~~with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers~~ wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

6. A non-rotating anatomical-shaped breast implant for being implanted within a body, wherein the body includes front, rear, right and left sides, with the non-rotating anatomical-shaped breast implant comprising:

a) an envelope formed in the anatomical shape of a breast, wherein the envelope comprises front, rear, right and left sides;

b) wherein the envelope is fillable with fill material;

c) wherein the front side of the envelope comprises a relatively smooth surface;

d) wherein the rear side of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the implant has been implanted such that the envelope is restrained from rotating and such that the front, rear, right and left sides of the envelope remain respectively oriented toward the front, rear, right and left sides of the body; and

e) wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

26. (currently amended) A non-rotating implant for being implanted within a body, wherein the body includes front, rear, right and left sides, with the implant comprising:

a) an envelope, wherein the envelope comprises front, rear, right and left sides;

b) wherein the envelope is fillable with fluid fill material;

c) wherein the front side of the envelope comprises a relatively smooth surface;

d) wherein the rear side of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the implant has been implanted such that the envelope is restrained from rotating and such that the front, rear, right and left sides of the envelope remain respectively oriented toward the front, rear, right and left sides of the body;

e) wherein the envelope is sealable after being filled with said fluid fill material, and wherein said front side having said relatively smooth surface is one-piece with said rear side having said relatively rough surface; and

f) ~~with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers~~ wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

8. A breast implant comprising:

a) an envelope having an anterior side, posterior side, superior pole, inferior pole and a nipple position, with the nipple position being on the anterior side near the inferior pole;

b) wherein the anterior side has a first thickness;

c) wherein the posterior side has a second thickness;

d) wherein the first thickness of the anterior side is less than the second thickness of the posterior side; and

e) wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

28. (currently amended) An implant comprising:

a) an envelope having an anterior side, posterior side, superior pole, and inferior pole;

b) wherein the anterior side has a first thickness;

c) wherein the posterior side has a second thickness;

d) wherein the first thickness of the anterior side is less than the second thickness of the posterior side;

e) wherein the envelope is sealable after being filled with fluid, and wherein said anterior side is one-piece with said posterior side; ~~and~~

f) ~~with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers~~ wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece; and

g) wherein the posterior side comprises a textured exterior surface portion.

14. A method for minimizing rotation of a breast implant within a body, comprising the steps of:

a) selecting a breast implant having an envelope, wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece, with the step of selecting a breast implant comprising the step of forming a relatively thin envelope side and a relatively thick envelope side with each other;

b) forming a relatively rough surface on an exterior portion of the relatively thick envelope side of the breast implant and forming a relatively smooth surface an exterior portion of the relatively thin envelope side of the breast implant;

c) implanting the breast implant within the body so as to orient the relatively smooth surface in a desired direction; then

d) permitting tissue growth to engage the relatively rough surface so as to anchor the breast implant in place, thereby minimizing rotation of the breast implant and holding the relatively smooth surface and relatively thin envelope side in the desired direction.

33. (currently amended) A method for minimizing rotation of an implant within a body, comprising the steps of:

a) selecting an implant having an envelope, wherein the envelope is sealable after being filled with fluid, with the step of selecting an implant comprising the step of forming a relatively thin envelope side and a relatively thick envelope side such that said relatively thin envelope side is one-piece with said relatively thick envelope side, and wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece;

b) forming a relatively rough surface on an exterior portion of the relatively thick envelope side of the implant and forming a relatively smooth surface an exterior portion of the relatively thin envelope side of the implant;

c) implanting the implant within the body so as to orient the relatively smooth surface in a desired direction; and then

d) permitting tissue growth to engage the relatively rough surface so as to anchor the implant in place, thereby minimizing rotation of the implant and holding the relatively smooth surface and relatively thin envelope side in the desired direction; ~~and~~

~~f) with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers~~.

17. A non-rotating breast implant for being implanted within a body, wherein the body includes front, rear, right and left sides, with the non-rotating breast implant comprising:

a) an envelope, wherein the envelope comprises front, rear, right and left sides;

b) wherein the envelope is fillable with fill material;

c) wherein the front side of the envelope comprises a relatively smooth surface;

d) wherein the rear side of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the implant has been implanted such that the envelope is restrained from rotating and such that the front, rear, right and left sides of the envelope remain respectively oriented toward the front, rear, right and left sides of the body; and

e) wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

36. (currently amended) A non-rotating implant for being implanted within a body, wherein the body includes front, rear, right and left sides, with the non-rotating implant comprising:

a) an envelope, wherein the envelope comprises front, rear, right and left sides;

b) wherein the envelope is fillable with fluid fill material;

c) wherein the front side of the envelope comprises a relatively smooth surface;

d) wherein the rear side of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the implant has been implanted such that the envelope is restrained from rotating and such that the front, rear, right and left sides of the envelope remain respectively oriented toward the front, rear, right and left sides of the body;

e) wherein the envelope is sealable after being filled with said fluid fill material, and wherein said front side having said relatively smooth surface is one-piece with said rear side having said relatively rough surface; and

f) ~~with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers~~ wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

Applicant respectfully submits that the present application is now in condition for allowance. The Examiner is respectfully invited to make contact with the undersigned by telephone if such would advance prosecution of this case.

Respectfully submitted,

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Robert J. Jacobson
Reg. No. 32,419

Tel. No.: (651) 699-7900
Fax. No.: (651) 699-7901

650 Brimhall Street South
St. Paul, MN 55116-1511